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Original Article

Evaluation of the harmonic scalpel in breast conserving and axillary staging surgery

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Abstract

Background: The ultrasonically activated scalpel has been introduced as an alternative to conventional methods of hemostasis in surgical procedures. The present study investigated the benefits of using the Harmonic FOCUS (HF) scalpel in breast-conserving surgery (BCS) and in axillary staging surgery.

Methods: All early-stage breast cancer patients who underwent BCS and axillary staging surgery between January 2009 and December 2010 were retrospectively identified. Those patients treated with the HF scalpel were defined as the HF group, while patients whose surgery involved the electrocautery and the clamp-and-tie technique were designated as the conventional method (CM) group. Both groups were subsequently divided into the axillary lymph node dissection (ALND) and sentinel lymph node biopsy (SLNB) subgroups, respectively.

Results: A total of 89 patients were included in the study, with 41 patients in the HF group and 48 in the CM group. There were 13 patients in the SLNB subgroup and 28 were in the ALND subgroup of the HF group, and 21 patients were in the SLNB subgroup and 27 in the ALND subgroup of the CM group. Multiple linear regression analysis revealed that the length of surgery was significantly reduced in the ALND subgroup of the HF group ($\beta = -16.70, p < 0.001$). The incidence of axillary numbness was significantly decreased in the ALND subgroup of the HF group, with the results measured by multiple logistic regression analysis ($OR = 0.27, p = 0.044$). No statistically significant differences were identified concerning intraoperative blood loss, postoperative drainage, and seroma between the HF and CM groups.

Conclusion: Using the Harmonic FOCUS scalpel in breast conserving surgery and axillary lymph node dissection significantly reduced the length of surgery and decreased the axillary numbness rate as compared to conventional methods.

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Keywords: axillary dissection; breast conserving; electrocautery; harmonic scalpel

1. Introduction

Less invasive procedures are currently being introduced into the clinical management of patients with breast cancer. Among these procedures, breast-conserving surgery (BCS) followed by radiotherapy has been proven to produce an outcome equal to a mastectomy.¹ Another such procedure is

the sentinel lymph node biopsy (SLNB), which can provide access to axillary nodal status and avoid an unnecessary axillary lymph node dissection (ALND) procedure in women with node-negative breast cancer.^{2,3} These procedures can reduce the possibility of operation-related complications. However, even with these improvements in surgical technique, breast surgeons continue to be challenged by morbidities associated with wound hematoma, wound infection, seroma, and axillary numbness.

The conventional method (CM) of breast cancer surgery is typically performed using a monopolar electrocautery and a clamp-and-tie technique for vessel ligation. Although

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electrocautery may reduce intraoperative blood loss, it has been postulated to be a factor for the risk of post-operative seroma formation and thermal injury to the adjacent nerve.^{4,5} The clamp-and-tie technique is considered to be safe and effective, but it is a time-consuming procedure.

The harmonic scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA) was introduced as an alternative to CM of hemostasis in surgical procedures about 2 decades ago. This instrument is used for cutting and coagulating tissues by producing high-frequency vibrations within the harmonic frequency range. This device generates a lower temperature elevation and reduces the spread of heat into the adjacent tissues as compared to electrocautery.⁶ However, even a small amount of thermal damage will contribute to the safety of dissection close to the nerve.⁷ The new Harmonic FOCUS (HF) Curved Shear (Ethicon Endo-Surgery) was designed with the familiar “Kelly clamp” in a shape that permits delicate and precise dissection in a small open surgical field. This tool has often been associated with a shorter operative time, less blood loss, and less postoperative pain when used in thyroidectomies.⁸

The results of several studies on the effect of the harmonic scalpel in breast cancer surgeries were varied.^{9–13} To our knowledge, the safety and efficacy of this novel HF tool in breast cancer surgery has not been thoroughly investigated. The purpose of this study was to compare the results between using the HF device in BSC and axillary staging surgery or proceeding using CMs.

2. Methods

The study was approved by the Institutional Review Board of our institution. We performed a retrospective review on all patients who underwent BCS and axillary staging surgery at a single institution, which were conducted by the same senior surgeon for a period of 2 years from January 2009 to December 2010. Patient information was collected from an actively maintained database. Our eligible criteria included women with unilateral high-grade ductal carcinoma in situ (DCIS) or invasive breast cancer stage T1-2 without clinically involved axillary nodes. The patients with surgeries that were performed using the HF were enrolled in the HF group. The patients whose surgeries were done using electrocautery and the clamp-and-tie method were included in the CM group. Both groups were further divided into the sentinel lymph node biopsy (SLNB) subgroup and the axillary lymph node dissection (ALND) subgroup.

The operative technique was standardized and differed only by the instruments used for dissection and hemostasis. In the CM group, breast tissue dissection and cutting was performed exclusively with monopolar electrocauterization, after the initial scalpel incision. Hemostasis was achieved through the traditional clamp-and-tie method. In the HF group, the HF scalpel was used exclusively for all dissection, cutting, and hemostasis, without the use of the clamp-and-tie technique. Power level 5 was applied in the breast dissection and power level 3 was used in the axillary dissection, close to the nerve to maximize safety. The SLNB was performed using an isotope 40 megabecquerels of technetium-99m-labeled Phytate

(Daiichi RI Laboratory, Tokyo, Japan), with intraoperative detection via a gamma probe. All patients with positive SLN or unidentified SLN underwent a level I and II axillary clearance (ALND subgroup). The second intercostobrachial nerve (ICBN) was preserved routinely. Two closed suction drains were inserted, one in the axilla and the other in the breast. Drains inserted in the chest wall were removed within 24 hours. Drains placed in the axilla were normally retained for one day after the SLNB and 4 days after the ALND unless the daily output was more than 30 ml. Postoperative compression dressings were employed for 2 days.

The medical records were reviewed for demographic data, clinical presentation, intraoperative blood loss, operative time, and postoperative data, including the amount of breast and axillary drainage, seroma, and the presence or absence of axillary numbness. Seroma was diagnosed clinically when aspiration was indicated. Patients with stage 0 or stage I (T1a.b N0) disease did not receive adjuvant chemotherapy; instead, planning computed tomography (CT) for radiotherapy was done in postoperative Weeks 3 to 6. Two trained radiologists later reviewed the contouring of the seroma on the CT images of these patients. It was recommended that all of the women return to the surgical outpatient department for follow-up 3 months after the operation. Numbness of the upper arm, axilla, and chest wall were assessed with direct physical examination. If the patient either complained or had a positive physical examination, then these findings were recorded as positive.

Statistical analysis was performed using SPSS 15.0 software (SPSS Inc, Chicago, IL, USA). The student's t-test and multiple linear regressions were used for continuous variables, whereas the χ^2 test and multiple logistic regressions were employed for categorical situations. Fisher's exact test was applied when small numbers were encountered and a two-tailed test of $p < 0.05$ was considered significant.

3. Results

A total of 89 patients had accessible medical records, with 41 patients in the HF group and 48 in the CM group. A total of 13 patients were in the SLNB subgroup and 28 were in the ALND subgroup of the HF group. A total of 21 patients were in the SLNB subgroup and 27 in the ALND subgroup of the CM group. Table 1 summarizes the patient demographics and clinical presentation of the two study groups. No statistically significant differences between the HF group and the CM group were identified with respect to age, body mass index (BMI), histopathologic diagnosis, tumor size, number of nodes dissected, and number of nodes with metastasis. The mean operative time (Table 2) was significantly shorter for the ALND subgroup of the HF group than for the CM group (71 minutes vs. 88 minutes; $p < 0.001$). As for the SLNB subgroups, the mean operative time revealed no statistically significant difference ($p = 0.131$). After controlling for age, BMI, tumor size, and number of lymph nodes dissected, the multiple linear regression analysis indicated that the operative time in the ALND subgroup of the HF group was significantly shorter than the CM group [$\beta = -16.70$, 95% confidence

Table 1
Demographic and clinical presentation of the HF group and the CM group.

	HF group <i>n</i> = 41 (46%)	CM group <i>n</i> = 48 (54%)	<i>p</i>
Age (yrs) ^a	55.3 ± 12.3	50.9 ± 9.4	0.058
BMI ^a	23.5 ± 3.5	24.4 ± 4.2	0.311
Diagnosis			
DCIS	9 (22.0%)	8 (16.7%)	0.293
Invasive cancer	32 (78.0%)	40 (83.3%)	
Group			
SLNB	13 (31.7%)	21 (43.8%)	0.172
ALND	28 (68.3%)	27 (56.3%)	
Tumor size (mm) ^a	21.5 ± 11.8	18.6 ± 9.2	0.198
Number of nodes dissected ^a	10.0 ± 7.2	8.5 ± 5.7	0.158
SLNB subgroup ^a	2.0 ± 1.0	2.3 ± 1.0	0.115
ALND subgroup ^a	13.8 ± 5.5	12.9 ± 3.5	0.473
Nodes with metastasis ^a	1.7 ± 5.2	1.3 ± 2.2	0.576

ALND = axillary lymph node dissection; BMI = body mass index; CM = convention method; DCIS = ductal carcinoma in situ; HF = Harmonic FOCUS; SD = standard deviation; SLNB = sentinel lymph node biopsy.

^a Mean ± SD.

Table 2
Intraoperative parameters related to the technique applied.

	HF group (<i>n</i> = 41)	CM group (<i>n</i> = 48)	<i>p</i>
Blood loss (ml)	27.3 ± 6.8	27.8 ± 6.4	0.724
SLNB	23.1 ± 4.4	26.4 ± 5.7	0.080
ALND	29.3 ± 6.9	28.9 ± 6.7	0.830
Operative time (min)	67.7 ± 9.0	78.1 ± 15.8	0.001
SLNB	61.2 ± 9.6	65.7 ± 7.5	0.131
ALND	71.3 ± 8.8	87.8 ± 13.6	<0.001

All values present mean ± SD. ALND = axillary lymph node dissection; CM = convention method; HF = Harmonic FOCUS; SD = standard deviation; SLNB = sentinel lymph node biopsy.

interval (CI) = −23.48 ~ −9.92, *p* < 0.001; Table 3]. No statistically significant difference was found in the intraoperative blood loss for either method and in either subgroup (Table 4). There was no significant difference between the two groups in terms of the amount of postoperative drainage of either the breast or the axilla. The incidence of subsequent aspiration of seroma and seroma noted by CT (HF, 12; CM,

Table 3
Multiple linear regression analysis of operative time.

	All patients (<i>n</i> = 89)			SLNB subgroups (<i>n</i> = 34)			ALND subgroups (<i>n</i> = 55)		
	β	95% CI	<i>p</i>	B	95% CI	<i>p</i>	β	95% CI	<i>p</i>
Technique									
CM	ref			ref			ref		
HF	−12.51	−17.38–−7.64	<0.001	−1.31	−8.30–5.69	0.704	−16.70	−23.48–−9.92	<0.001
Age (yrs)	0.09	−0.13–0.32	0.416	−0.03	−0.31–0.25	0.831	0.10	−0.23–0.42	0.550
BMI	0.15	−0.46–0.76	0.629	−0.04	−0.77–0.69	0.913	−0.02	−1.01–0.97	0.967
Tumor size	0.05	−0.20–0.30	0.678	0.30	−0.06–0.65	0.095	0.01	−0.34–0.36	0.963
LN dissected	−0.10	−0.77–0.56	0.762	2.14	−0.80–5.07	0.147	−0.05	−0.81–0.71	0.894
Subgroup									
SLNB	ref								
ALND	17.84	9.44–26.25	<0.001						

ALND = axillary lymph node dissection; BMI = body mass index; CI = confidence interval; CM = convention method; HF = Harmonic FOCUS; LN = lymph node; SD = standard deviation; SLNB = sentinel lymph node biopsy.

Table 4
The volume amount from the breast and axillary drain.

	HF group (<i>n</i> = 41)	CM group (<i>n</i> = 48)	<i>P</i>
Chest wall drain (ml)	32.3 ± 10.9	35.9 ± 11.5	0.143
Axillary drain (ml)	28.7 ± 9.8	30.9 ± 14.4	0.414
SLNB, 24 hr	24.0 ± 9.5	23.3 ± 12.0	0.857
ALND, 24 hr	31.0 ± 9.2	37.0 ± 13.4	0.064
ALND, total	60.4 ± 27.9	67.9 ± 48.3	0.494

All values present mean ± SD. ALND = axillary lymph node dissection; CM = convention method; HF = Harmonic FOCUS; SD = standard deviation; SLNB = sentinel lymph node biopsy.

14) had no statistically significant difference (Table 5). Significantly fewer incidences of axillary numbness were observed in the ALND subgroup of the HF group [7/28 (25.0%) vs. 15/27 (55.6%); *p* = 0.020; Table 5). Axillary numbness was also seen less often in the SLNB subgroup of the HF group (1/13 vs. 3/21), yet had no statistical significance (*p* = 0.502). When controlled for age, BMI, tumor size, and the number of lymph nodes dissected, multiple logistic regression analysis revealed that the frequency of occurrences of postoperative numbness in the ALND subgroup of the HF group were significantly fewer than in the CM group (OR = 0.27, 95% CI = 0.07 ~ 0.96, *p* = 0.044; Table 6).

4. Discussion

The harmonic scalpel is an innovative device that vibrates at 55.5 kHz and causes three synergistic effects: cavitation, coagulation, and cutting to achieve effective hemostasis and tissue dissection at a precise point. With its advantage of reduced thermal spread that lowers the incidence of adjacent tissue destruction,^{6,7} this instrument has been approved by the U.S. Food and Drug Administration (FDA) for ligation of vessels up to 5 mm in diameter. The safety and advantages of the harmonic scalpel have been reported for surgeries in several anatomical regions.^{14–17}

Deo and Shukla⁹ were the first to describe their experience utilizing the harmonic scalpel in a modified radical mastectomy in 2000. They reported a decrease in blood loss and

Table 5
Incidence of postoperative complications.

	HF group (n = 41)	CM group (n = 48)	p
Seroma	6/41 (14.6%)	6/48 (12.5%)	0.504
Asp	3/41 (7.3%)	3/48 (6.3%)	0.583
CT	3/12 (25.0%)	3/14 (21.4%)	0.596
Numbness	8/41 (19.5%)	18/48 (37.5%)	0.051
ALND	7/28 (25.0%)	15/27 (55.6%)	0.020
SLNB	1/13 (7.7%)	3/21 (14.3%)	0.502

ALND = axillary lymph node dissection; Asp = number of cases of seroma aspirated following drain removal; CM = convention method; CT = number of cases of seroma detected by planned computed tomography; HF = Harmonic FOCUS; SLNB = sentinel lymph node biopsy.

duration of drainage as compared to the standard clamp-and-tie technique.¹⁸ Some studies have been published since these early trials, but none of them corroborated the benefits of the harmonic scalpel in breast cancer surgery. Galatius *et al.*¹⁰ found no differences in operative time, blood loss, and seroma volume in patients receiving modified radical mastectomies. Sanguinetti *et al.*¹³ reported the use of the harmonic scalpel as compared to electrocautery in performing axillary dissection and noted a significant decrease in blood loss and drainage duration, but no significant difference in the operating time. However, these studies were conducted using the old, cumbersome harmonic scalpel. The newly designed HF device is a more convenient device for dissecting within a superficial open field than the previous harmonic scalpel. Nevertheless, the HF can be applied for dissection to nearly all the operative steps in breast cancer surgery.

In the present study, there were no significant differences in the intraoperative blood loss in either group, probably because both HF and CM have been proven to be safe and effective methods for dissection and hemostasis. Harmonic scalpels incise the tissue more slowly than electrocautery because of their mechanism of action.⁷ Hence, the timeframe for a BCS procedure will not be reduced using the HF. This could be a reason why Galatius *et al.*¹⁰ reported no differences in the operative time with patients undergoing modified radical mastectomy with a large volume of breast tissue excised.

However, the mean operative time was significantly shorter for the HF group in our study than for the CM group. Further analysis showed that the mean operative time was significantly reduced in the ALND subgroup of the HF group than in the CM group. In contrast, the mean operative time was not significantly different in the SLNB subgroups of either the HF or CM groups. Such a difference may result from the frequent use of the clamp-and-tie technique during the ALND procedure, which was replaced by the use of the HF. Conversely, there were fewer uses of clamp-and-tie in the SLNB procedure.

Seroma formation is the most common early sequela to breast cancer surgery. Previous literature has suggested that the increased incidence of seroma formation was attributable to the thermal trauma from electrocautery dissection.¹⁹ However, Kontos *et al.*¹² found no significant reduction in seroma formation, wound complications, and postoperative pain with the use of the old harmonic scalpel. This is consistent with our experience using the new HF, where there were no differences between the postoperative drainage volume and the incidence of seroma formation in either the HF or CM groups.

The second ICBN supplies the skin of the medial wall and the floor of the axilla, as well as the medial side of the upper part of the arm. The loss of sensitivity was significantly lowered when the ICBN was preserved.²⁰ Axillary numbness was commonly seen after an ALND, but much less frequently after an SLNB.²¹ This morbidity was due to not sparing the ICBN when performing the ALND. Nevertheless, even with the ICBN preserved, incidences of sensory deficit were as high as 53%,²² which is a possible outcome of an inadvertent injury to the lower ICBN.²¹ HF may be safer than electrocautery for dissection near the nerves.⁷ In our study, the number of patients with axillary numbness after their ALND was significantly reduced in the HF groups. This may be attributable to the lower heat spread and the lack of risk of electrical injury from the HF. However, there were no statistically significant changes in the incidences of axillary numbness after the SLNB between the HF and CM groups because of the small number of cases where

Table 6
Multiple logistic regression analysis of the incidence of postoperative numbness.

	All patients (n = 89)			SLNB subgroups (n = 34)			ALND subgroups (n = 55)		
	OR	95% CI	p	OR	95% CI	p	OR	95% CI	p
Technique									
CM	ref			ref			ref		
HF	0.31	0.10–0.97	0.044	2.45	0.10–57.96	0.579	0.27	0.07–0.96	0.044
Age (yrs)	0.98	0.93–1.04	0.516	0.93	0.81–1.07	0.313	0.99	0.93–1.05	0.688
BMI	1.16	1.01–1.35	0.041	0.99	0.74–1.32	0.923	1.18	0.97–1.44	0.089
Tumor size	1.00	0.95–1.06	0.921	1.11	0.95–1.29	0.184	0.99	0.93–1.06	0.798
LN dissected	1.09	0.95–1.25	0.210	1.97	0.41–9.37	0.395	1.10	0.96–1.27	0.180
Subgroup									
SLNB	ref								
ALND	3.22	0.48–21.79	0.230						

ALND = axillary lymph node dissection; BMI = body mass index; CI = confidence interval; CM = convention method; HF = Harmonic FOCUS; LN = lymph node; SLNB = sentinel lymph node biopsy.

this complication had occurred [1/13 (7.7%) vs. 3/21 (14.3%); $p = 0.502$].

This study is limited in that it is a retrospective review from one surgeon at a single institution. This potentially removes the variations associated with different surgeons' techniques and experience, but possibly makes our results less applicable generally. However, our results are in concurrence with similar studies.^{10,23} Therefore, our results may not have been adversely affected by having only one surgeon perform all surgical procedures.

In conclusion, the HF is a safe instrument producing results similar to the standard CM. The use of HF in BCS and ALND procedures significantly reduced both operative time and incidences of axillary numbness. There were no significant operative benefits of HF during BCS and SLNB procedures.

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